

K120724

MAY - 7 2012

**510(k) Summary**

**Sponsor:**

Pioneer Surgical Technology  
375 River Park Circle  
Marquette, MI 49855  
(906) 225-5861  
Contact: Sarah McIntyre, Emily M. Downs  
Date: May 3, 2012

**Device Name:**

Pioneer Lateral Plate System

**Classification Name:**

Spinal Intervertebral Body Fixation Orthosis

**Classification:**

Regulation Number: §888.3060 Spinal intervertebral body fixation orthosis

Product Code: KWQ; Panel Code: 87

**Predicate Devices:**

• NuVasive Lateral Plate System (K070273)  
Quantum Spinal System (K080518)  
Pioneer Lumbar Plate System (K090222)

**Description:**

The Pioneer Lateral Plate System consists of an assortment of plates and screws manufactured from ASTM F136 Titanium Alloy.

**Intended Use:**

The *Pioneer Lateral Plate System* is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

**Performance Data:**

ASTM F1717 Dynamic axial compression, static axial compression and torsional static testing were performed, in addition to ASTM F543 screw pull-out and screw pull-through testing, to establish substantial equivalence. The test results demonstrate that the Pioneer Lateral Plate System functioned as intended and performed in a manner substantially equivalent to that of predicate systems.

**Performance and SE Determination:**

Equivalence for the Pioneer Lateral Plate System is based on similarities of intended use, design, and physical characteristics when compared to predicate devices. Therefore, Pioneer Surgical Technology believes that there is sufficient evidence to conclude that the Pioneer Lateral Plate System is substantially equivalent to existing legally marketed devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Pioneer Surgical Technology  
% Ms. Sarah McIntyre  
Regulatory Affairs Associate  
375 River Park Circle  
Marquette, Michigan 49855

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-G609  
Silver Spring, MD 20993-0002

MAY - 7 2012

Re: K120724

Trade/Device Name: Pioneer Lateral Plate System  
Regulation Number: 21 CFR 888.3060  
Regulation Name: Spinal intervertebral body fixation orthosis  
Regulatory Class: Class II  
Product Code: KWQ  
Dated: March 7, 2012  
Received: March 9, 2012

Dear Ms. McIntyre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



f - Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## 2.0 Indications for Use Statement

510(k) Number (if known): K12 0724

Device Name: Pioneer Lateral Plate System

Indications: The *Pioneer Lateral Plate System* is indicated for use via the lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

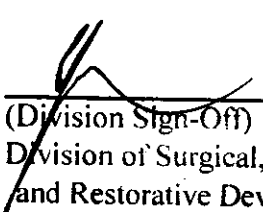
Prescription-Use ✓  
(Per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K120724